Foreword and acknowledgments

Founded in 1949, the Council of Europe is the oldest and largest of all European institutions and now numbers 47 member states. One of its founding principles is that of increasing co-operation between member states to improve the quality of life for all Europeans.

Within this context of inter-governmental co-operation in the field of health, the Council of Europe has consistently selected ethical problems for study. One of the most important of these ethical issues relates to the non-commercialisation of human substances, i.e. blood, organs, tissues and cell.

Transplant medicine and transplantation have progressed during recent decades in a way nobody would have imagined years before. As with organs, the demand for some transplantable tissues far outweighs the available supply. This has critical results, considering that human cells and tissues for transplantation can save lives or restore essential functions. For example, a corneal graft can restore sight in corneal blindness, having skin available for a traumatic burn can be critical for patient survival and the transplantation of haematopoietic stem cells can cure congenital or acquired diseases, including some leukaemias.

1 Albania, Andorra, Armenia, Austria, Azerbaijan, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Georgia, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Republic of Moldova, Monaco, Montenegro, Netherlands, Norway, Poland, Portugal, Romania, Russian Federation, San Marino, Serbia, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, “the former Yugoslav Republic of Macedonia”, Turkey, Ukraine, United Kingdom.
Human cells and tissues for transplantation represent a special class of basic healthcare products, as well as being the potential starting material for much more complex biotechnology products in the future. As with all transplanted material of human origin, they carry risks of disease transmission, which must be controlled by the application of scrupulous donor selection and testing criteria and comprehensive quality systems.

Since 2002, the European Committee (Partial Agreement) on Organ Transplantation of the Council of Europe (CD-P-TO) has been publishing the Guide to the safety and quality assurance for the transplantation of organs, tissues and cells. This Guide deals with different aspects of the transplantation process, from risk assessment to disease transmission. During the last revision process, it became evident that the fields of organ transplantation and tissue and cell transplantation have different safety and quality provisions and concerns, thereby justifying the existence of two different guides. Therefore, the CD-P-TO has decided to separate the existing guidance into two new guides; one that deals with organs and the other with tissue- and cell-specific requirements. This 1st edition of the Guide to the quality and safety of tissues and cells for human application collates updated information to provide transplant professionals with a useful overview of the most recent advances in the field. To increase safety for recipients of tissues and cells, it is essential that professionals involved in identifying potential donors, transplant co-ordinators managing the donation process, procurement units, tissue establishments processing and storing tissues and cells, inspectors auditing these establishments and end users have easy access to this information.

This Guide has been divided into two parts. Part A contains general requirements applicable to all establishments involved in the donation, procurement, testing, processing, preservation, storage and distribution of tissues and cells. Part B contains specific guidelines and requirements for the different tissue and/or cell types. The general guidelines of Part A also apply to tissues that have not been included in Part B of the present edition because they are less commonly used (e.g. parathyroid tissue, neural tissue, etc.). Use of the word “must”
indicates mandatory compliance and alignment with European Directives, whereas use of the word “should” indicates recommended compliance. In addition, unless otherwise stated, the guidelines apply only to tissues and cells intended for clinical use or transplantation (including insemination and fertilisation). Tissues and cells used for “basic” research do not fall under the scope of the present Guide.

This Guide has been the work of many people. The work has been co-ordinated by the Centro Nazionale Trapianti (CNT; tissues) and Agence de la Biomédecine (ABM; cells), but a number of experts must be acknowledged for their contributions and efforts and in the discussions on various parts of this Guide. In particular, Deirdre Fehily (Italy) has put enormous amounts of energy, time, expertise and dedication into making sure the 1st edition of this Guide is a reality. Some other experts should be specifically acknowledged, including:

Anna Vilarrodona i Serrat, Spain
Boryana Avramova, Bulgaria
Carl-Ludwig Fischer-Fröehlich, Germany
Carolina Stylianou, Cyprus
Catherine Faucher, France
Christian Chabannon, France
Efstratios Chatzixiros, Italy
Eliana Porta, Italy
Eliisa Lukk, Estonia
Elisa Pianigiani, Italy
Elba Agustí i Rovira, Spain
Esteve Trias, Spain
Fewzi Teskrat, France
Fiorenza Bariani, Italy
Gorazd Cebulc, Slovenia
Hervé Creusvaux, France
Imogen Swann, United Kingdom

Iván Miranda Álvarez-Pickman, Spain
Jaime Tabera Fernández, Spain
Letizia Lombardini, Italy
Ludo Muylle, Belgium
Margarida Amil, Portugal
Óscar Fariñas Barbera, Spain
Patrick Costello, Ireland
Ralf R. Tönjes, Germany
Renuka Sornarajah, United Kingdom
Rosana Maria Cristina Turcu, Romania
Ruth M. Warwick, United Kingdom
Scott A. Brubaker, United States of America
Utku Ates, Turkey
These experts contributed to different aspects of the book and did a tremendous job in reviewing the literature and extracting knowledge from numerous international guidelines, collaborative projects and diverse publications and websites with the aim of ensuring accessibility to all this information.

Special thanks should be given to the European Commission, in particular to Ioana-Raluca Siska, who ensured the current text remained aligned with European Directives and made available the results from the European Union-funded projects EQSTB, EUSTITE, EuroGTP and SOHO V&S.

Several professional organisations, especially the American Association of Tissue Banks (AATB), the European Association of Tissue Banks (EATB) and the Joint Accreditation Committee-ISCT & EBMT (JACIE), should also be thanked for sharing their experience and knowledge.

Finally, the scientific Secretariat and editorial team at the European Directorate for the Quality of Medicines & HealthCare (EDQM), Council of Europe, in Strasbourg should be acknowledged: Marta López Fraga, Scientific Officer responsible for the transplantation activities at the Council of Europe and Ahlem Sanchez, John O’Brien, David Crowe and Isabelle Bylinski for their work on the administrative and editorial aspects of this publication. An extended thank-you should also be given to Karl-Heinz Buchheit, Head of the Department of Biological Standardisation, OMCL Network & HealthCare (DBO), and Susanne Keitel, Director of the EDQM.

All this has been a great combined effort, with extensive discussions dedicated towards the common goal of increasing safety, efficacy and quality in tissue and cell donation and transplantation. The final result is this Guide, which constitutes a common European standard, based on the long-standing expertise and knowledge of the EDQM.